

C.U.SHAH UNIVERSITY

Wadhwan City

Subject Code : **5PS02PHA1**

Summer Examination-2014

Date: 27/06/2014

Subject Name: **Pharmaceutical Analysis- I**Branch/Semester: **M.Pharm/II**

Time: 02:00 To 5:00

Examination: **Regular****Instructions:-**

- (1) Attempt all Questions of both sections in same answer book / Supplementary
- (2) Use of Programmable calculator & any other electronic instrument is prohibited.
- (3) Instructions written on main answer Book are strictly to be obeyed.
- (4) Draw neat diagrams & figures (If necessary) at right places
- (5) Assume suitable & Perfect data if needed

SECTION I**Q-1 Define Following terms/Concepts 7**

- a) Precision
- b) Accuracy
- c) LOD
- d) LOQ
- e) Ruggedness
- f) Robustness
- g) Internal Standard for Analytical method

- Q-2**
- a) Write a note on Quality control test for Lipsticks and Face powder (5)
 - b) Write a note on quality control test for Hair oil, Hair Colour, Hair Straightening Cream and Hair Cream (5)
 - c) Write a note on QC test for Body lotion and Shampoo (4)

OR

- Q-2**
- a) Write a note on quantitative estimation of Hydroxyl group containing compound (5)
 - b) Write a note on quantitative estimation of Carboxylic acid Group containing compounds (5)
 - c) Write a note on quality control of Raw material used in cosmetics (4)

- Q-3 14**
- a) Define Preservative and Antioxidants. Explain method of analysis for any two preservative and antioxidants.
 - b) Write a note on quality control of radiopharmaceuticals.

OR

- Q-3 14**
- a) What is the use of emulsifier and stabilizer in pharmaceutical formulation? Write a note on qualitative and quantitative estimation of emulsifier and stabilizer.
 - b) Define colouring agent. What are the different types of colouring agents? Give 2 examples of each class. Write a note on estimation of colouring agents



SECTION II

- Q-4
- a) What will happen to the atomic number and atomic mass of the atom when it will omit a alpha (α), or a beta (β) or a gamma (γ) ray? 3
 - b) What are different types of production of radioactive nuclide? 2
 - c) Define various units of radioactivity. 2
- Q-5
- a) Write a brief note on ICH Q1 guideline. 5
 - b) Write a note on impurity profiling using LC-MS 5
 - c) Write a case study on impurity profiling 4
- OR**
- Q-5
- a) Write a note on Stability indicating Assay by Acid hydrolysis, Base hydrolysis and Oxidative hydrolysis 5
 - b) Discuss the solid state properties associated with bulk level 5
 - c) What is importance of SIA? Write a note on Stability indicating Assay by photolytic hydrolysis, thermal hydrolysis. 4
- Q-6
- a) Give a detail account on Quality control test of containers 14
 - b) Give a detail note on QC test of lables, label adhesive and cartons.
- OR**
- Q-6
- a) Give introduction of ICH with a detail note on the harmonization process. 14
 - b) Give a note on impurity isolation and characterization using LC-IR and LC-NMR

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